

## **REMARKS**

### **Amendments to the Specification:**

The Examiner objected to the disclosure of paragraph [0027] at page 6, line 10 because of a typographical error, and noted that the indicated line should read, "prior to seed placement." The correction from "see placement," as originally filed, has been made.

The Examiner further objected to the disclosure of paragraph [0065] at page 13, line 25 as containing an improper embedded link. Applicant has deleted the reference to the link in the revised paragraph as set forth above.

### **Allowed Claims:**

Applicant accepts the Examiner's allowance of claims 7-13 and 18. A notice of allowance respectfully is requested.

### **Objections to the Claims:**

The Examiner's objections to the informalities in claims 1, 5, and 17 have been addressed by making the appropriate corrections to those claims, as set forth at page 2 of the present Office Action.

Pursuant to the Examiner's objections to dependent claims 2-4 and 16 (Office Action at page 7), these claims have been re-written. Reconsideration of the objections and allowance of the new/re-written claims (nos. 26-29) is requested.

### **Amendments to the Claims:**

Claims 1, 2, 5-10, 13, 14, 16-18 are amended. Claim 15 is cancelled. Claims 19-29 are new. No new matter has been added.

### **Claim Rejections:**

#### **Rejections Based on 35 U.S.C. § 112 ¶ 2**

The Examiner rejected claims 1-6 under section 112, second paragraph as being indefinite. Specifically, the examiner indicated that the language "wherein at least any of the plurality of

treatment strands have a custom distal end spacing” fails to particularly point out and distinctly claim the subject matter of Applicant’s invention.

Applicant accordingly has revised the language of claim 1 definitely to claim custom end spacing for at least two of the plurality of treatment strands, as indicated in the amendments above. Claim 1 is now patentable. Claims 2-6 depend directly or indirectly from claim 1. Therefore the amendment to claim 1 renders patentable not only claim 1 but also rejected claims 2-6. Applicant therefore requests the Examiner’s reconsideration of the rejection of claims 1-6.

### **Rejection Based on 35 U.S.C. § 102(e)**

#### ***Lennox Reference***

The Examiner rejected claims 1 and 5 under section 102(e) as being anticipated by Lennox (U.S. Pat. No. 6,537,193) (“Lennox”). According to the Office Action, Lennox teaches a method of accepting a treatment plan specifying a number and spacing of treatment seeds to be provided in a plurality of treatment needles, creating the treatment strands, and aligning the treatment strands in a template. The Examiner notes that claim 1 as originally submitted claims “‘at least’ none ‘of the plurality of treatment strands have a custom distal end spacing.’”

Applicant respectfully notes that as currently amended, claim 1 now claims “*at least two of the plurality of treatment strands has a custom distal end spacing*” (emphasis added). The creating step now claims, “creating the plurality of treatment strands according to said tissue treatment plan; and wherein at least two of the plurality of treatment strands has a custom distal end spacing.” Lennox does not teach custom end spacing.

Moreover, Lennox does not teach using a polymeric material to encapsulate and position radioactive seed elements, as does the present invention. Instead, Lennox teaches delivering seeds with biodegradable spacers through needles arranged in a two-dimensional array according to a template; there is no “strand” as in the present invention:

The template consists of a matrix of holes that guide the longitudinal advancement of the needles to ensure their proper two-dimensional position in the tumor. Once the two-dimensional array of needles is established in the tumor, the seeds are deposited along the longitudinal axis of each needle. The spacing of the seeds along the longitudinal axis

of the needle is accomplished by using biodegradable spacers between the seeds.

Lennox, Col. 3, ll. 38-46. Lennox therefore does not anticipate independent claim 1 or dependent claim 5 of the present invention and accordingly, Applicant requests that the Examiner reconsider the rejection pursuant to section 102(e) based on Lennox.

**Rejection Based on 35 U.S.C. § 102(b)**

***Langton Reference***

The Examiner rejected claim 14 under section 102(b) as being anticipated by Langton et al. (U.S. Pat. No. 5,460,592) (“Langton”). According to the Office Action, Langton teaches a therapeutic device comprising a seed strand having a distal end, a plurality of seeds at spaced intervals along the strand, and a custom end space for the seed adjacent the distal end of the strand. Applicant respectfully disagrees that the claims defining the present invention are anticipated by the disclosure of Langton.

Claim 14 as amended claims a therapeutic device comprising, in relevant part, “custom end spacings according to a treatment plan provided between the seed located adjacent to the distal end of each said seed strand and the distal end of each said seed strand.” In contrast, the disclosure of Langton does not contemplate the use of customized end spacing or customized spacing of treatment seeds. Langton discloses a carrier assembly and method for preparing the carrier assembly using a spacing jig. Langton, Col. 1, ll. 7-10; Col. 2, ll. 48-50. The use of the spacing jig cannot permit *customized* end spacing, but rather, only *conventional spacing at fixed distances*:

The elongated material and seeds are placed in a spacing jig member which has a plurality of spaced, first and second recesses. The bio-absorbable, elongated material, generally in the form of a flexible, braided string, is disposed in the first recesses while radioactive seeds, which are spaced along the string material, are disposed within the second recesses. The second recesses are spaced a predetermined distance from one another.

Langton, Col. 2, ll. 48-55.

Moreover, there is no teaching in Langton addressing a physician's prescribed custom spacing of treatment seeds. In particular, Langton does not disclose or teach custom end spacing that enables implanting a plurality of treatment strands so that the strands all are positioned at a uniform depth in the tissue to be treated in a patient, while the seeds located adjacent to a distal end of each respective treatment strand are placed at potentially different depths relative to each other, to treat the tissue as required by a treatment plan for the patient, *i.e.*, to place the treatment seeds, which can be radioactive treatment seeds, near tissue to be irradiated by the seeds. Therefore, although the disclosure of Figure 1 of Langton shows a single strand with end spacing, Langton does not teach or disclose different end spacing among several treatment strands.

Accordingly, Langton does not anticipate the present invention of customized end spacing disclosed and claimed in the present application. It is submitted that claim 14 is patentable over the cited art. On this basis, Applicant requests the Examiner's reconsideration of his rejection based upon section 102(b) and Langton.

#### **Rejection Based on 35 U.S.C. § 103(a)**

The Examiner rejected claim 6 pursuant to section 103(a) for obviousness and unpatentability over Lennox. The Office Action states that while "[Lennox] does not teach a method, wherein all treatment strands are the same length," "[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to provide duplicate treatment strands having all the same length." Office Action at 5. Applicant respectfully disagrees.

Although Lennox teaches "custom spacers for a particular treatment regime . . .", Col. 4, l. 25, Lennox does not teach or suggest custom end spacing as disclosed or claimed in the present invention. Custom end spacing is the feature claimed in independent claim 1, from which claim 6 indirectly depends, which allows a physician using the invention to implant all customized therapeutic strands to the same depth, without identifying the distal end of the strand via imaging or visual inspection. With a spacer at the distal end of the treatment strand, as opposed to a treatment seed at the distal end, as in the cited art (*see, e.g.*, Lennox Figs. 1 and 2), the length of the spacer can be varied from strand to strand, while the overall length of the treatment strand remains the same, and all treatment strands can be implanted to the same depth. Lennox teaches away from the present

claimed method, since "image guidance" is necessary for placement of the seed placement device. Col. 4, ll. 6-9. The Examiner has cited no other art rendering obvious the present invention. Accordingly, Applicant respectfully requests reconsideration of the rejection under section 103(a) of claim 6.

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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